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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,784	11/26/2001	Robert G. Ulrich	003/233/SAP	6261

7590 07/03/2003

ATTN: MCMR-JA  
U. S. Army Medical Research,  
and Materiel Command  
504 Scott Street  
Fort Detrick, MD 21702-5012

EXAMINER

MINNIFIELD, NITA M

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 07/03/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/002,784	ULRICH, ROBERT G.
	<b>Examiner</b> N. M. Minnifield	<b>Art Unit</b> 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 05 May 2003.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-75 is/are pending in the application.  
4a) Of the above claim(s) 1-31,33,34,36-40 and 44-75 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 32,35 and 41-43 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) 1-31,33,34,36-40 and 44-75 are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 26 April 2002 is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some \* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) **3 Sheets** 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 5)  Notice of Informal Patent Application (PTO-152)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) **11**. 6)  Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicant's election of Group II, claims 32-43 and species SpeA, SEQ ID NO: 16, in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-31, 33, 34, 36-40 and 44-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and/or species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.
3. Claims 32, 35 and 41-43 are being examined in the present application since they are directed to the elected invention and species.
4. Applicants should update the continuing data found on page 1 of the specification.
5. The information disclosure statement filed March 7, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing or post office address of each inventor. A mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

“Lisa A. Ware” is listed as an inventor, however there is no additional information.

7. Claims 41-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is noted that Applicants elected species SpeA and SEQ ID NO: 16. Claim 41 recites that the position 42 of altered SpeA superantigen toxin peptide has been altered to alanine or arginine. However, upon review of SEQ ID NO: 16 (description streptococcal pyrogenic exotoxin A mutant) position 42 is serine not alanine or arginine as is recited in claim 41. Clarification is requested. Same for claims 42 and 43 and SEQ ID NO: 27 (a fusion mutant), the fusion SpeA-SpeB does not show that position 47 is serine as is recited in claim 42. Clarification is requested.

8. It is noted that the present application is a CIP of 08/882431 filed 6/25/97. SEQ ID NO: 16 is set forth in 08/882431. SEQ ID NO: 27 is not set forth in 08/882431. SEQ ID NO: 27 is first disclosed in the pending application and therefore gets a filing date of 11/26/01, the date of filing of the pending application. The effective filing date for claims 32, 35, 41 and 42 is 6/25/97. The effective filing date for claim 43 is 11/26/01.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Bavari et al 1996 or 1995 (Vaccines , 1996, 96:135-141; J. Infectious Diseases, 1996, 174:338-345; J. Cellular Biochemistry, 1996, Suppl. 21A:88, abstract #C2-207).

Claim 32 is directed to an isolated and purified superantigen toxin, which has been altered such that binding of the encoded altered, toxin to either the MHC class II or T cell antigen receptor is altered.

Bavari et al 1996 (Vaccine) discloses bacterial superantigens and that they bind to MHC class II molecules and T cell antigen receptors (p. 135, paragraph 1 and 4). Bavari et al also discloses that bacterial superantigens were designed by site-directed mutagenesis to eliminate (i.e. alter) receptor binding without

disturbing antigenic structure. The mutant proteins do not bind MHC class II receptors (p. 140).

Bavari et al (J. Infectious Diseases) discloses mutants of a bacterial superantigen that have altered binding to either the T cell antigen receptor or the MHC class II molecules (abstract; p. 338; p. 344).

Bavari et al (J. Cellular Biochemistry) discloses mutants of a bacterial superantigen that have altered binding to either the T cell antigen receptor or diminished MHC class II binding (abstract).

The prior art anticipates the claimed invention.

11. Claims 32, 35 and 41 are rejected under 35 U.S.C. 102(a) as being anticipated by Schlievert et al (WO 96/40930).

Schlievert et al discloses mutant of a bacterial superantigen, SpeA toxins (abstract). The prior art discloses that the mutant SpeA has at least one amino acid change and mutant SpeA has a change in biological function compared with the wild-type SpeA (p. 9) and decrease in T cell mitogenicity when compared to wild-type SpeA (p. 5). The prior art discloses the claimed invention.

12. No claims are allowed.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is

703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



N. M. Minfield

Primary Examiner

Art Unit 1645

NMM

June 25, 2003